Editorials

A New Look in Government Regulation?

SOME SORT OF REGULATION OR GOVERNANCE is essential if any complex system with many interdependent parts is ever to work smoothly—or at all. This is true of inanimate as well as animate systems. And it is true of human societies and of human systems within these societies. Health care is such a complex system within our own human society. But a satisfactory approach to its regulation and governance still eludes us. Certainly most of the efforts to regulate health care have created more problems than they solved, and almost no one has been satisfied with the results.

In the Medical News section of the October 25, 1985, issue of the *Journal of the American Medical Association (JAMA)*[1] there are a number of statements or reports concerning the present functions of the Food and Drug Administration (FDA) and how it prepares to "meet the regulatory challenges of the 21st century." One cannot help but be impressed with the extent of the FDA's interactions with other federal organizations ("working with virtually every federal agency") and with state and local governments, and its effect on almost every segment of the private sector in one way or another. Its charge, of course, is to protect the quality of the food we eat and of the drugs and medical devices that we use in health care. Significantly, its responsibilities fall short of health care delivery itself. Also, one can be even more impressed by what appears to be an evolutionary, perhaps even revolutionary, change in attitude in the agency toward developing and enforcing regulations. To be sure, the power of the federal government is still there, but there is an evident effort to be more closely in touch with the professions and the public, to seek and accept advice from them, and to use education of the profession, the public and others, along with reasonable regulations, to achieve the aims of the agency. The shift seems to be a softening of what has often been more of an adversarial approach in imposing and enforcing government regulations, toward more emphasis on genuine collaboration to achieve recognized common goals. In theory at least, this should result in better, more workable and more acceptable regulations from the FDA. One even senses that this more collaborative approach may even now be coming into place and beginning to work.

The food, drugs and medical devices regulated by the FDA and health care delivery have much in common. Both are complex technologic and social systems involving the health and well-being of individual citizens, and both interact with "virtually every federal agency," with state agencies, and in one way or another affect almost every segment of the private sector. And it is to be noted that both are at the cutting edge of modern society's still stumbling efforts to find ways of dealing with the complex and irreversible social, economic and political interdependencies that have been the inevitable result of the scientific and technologic advances that have occurred most particularly in recent decades.

Now let it be clear that this author in no way believes that health care should be given to the FDA to regulate. But the approach and activities of the FDA as described in the *JAMA* reports do suggest that the FDA may be on to something with its new, more collaborative approach toward necessary government regulation of the food and drug industry. Government regulation of health care delivery has so far been distinctly adversarial in tone, has been distinctly inefficient and costly and, in addition, has not been particularly successful in achieving its goals. Maybe the health care regulators should consider the new FDA approach, borrow a page from the FDA book and at least try a little more collaboration with the health professions, the autonomous and still relatively independent health care agencies and institutions, and with the public, both sick and well. This just might be the wave of the future for needed regulation of essential services in an increasingly interdependent society that is also dedicated to maintaining a maximum degree of freedom and independence for its individual citizens and for its interdependent component parts.

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Breast Cancer Detection

DATA CONTINUE TO ACCUMULATE supporting the potential reduction in breast cancer mortality by intensive screening. Improvements in mammographic technique can significantly reduce the radiation risk,[1] which may in fact be nonexistent for women over age 40 (according to A.B. Miller, MB, FRCP, Epidemiology Unit, National Cancer Institute of Canada [oral communication]). Screening clinics are opening across the country. The article by Margolin and Lagios in this month's journal shows that early detection using mammography is not a capability confined to the teaching hospitals but can be accomplished in a community setting if a thoughtful, carefully monitored program is developed. If screening is to result in reduced mortality, it requires this kind of carefully supervised approach using the highest quality mammography.

In the early 1960s a landmark screening study was undertaken by the Health Insurance Plan of New York (HIP) in which more than 60,000 women were randomly assigned into two groups. Half of the women were offered annual screening by physical examination and mammography for four years.[2] This study group was compared with the unscreened control population and in a 10- to 14-year follow-up a 25% to 35% mortality reduction was shown for women in the screening group.[3] The results of the HIP study led to the Breast Cancer Detection Demonstration Project (BCDDP) in the early 1970s in which more than 275,000 women underwent physical examination and mammographic screening in 27 centers across the United States. As the authors point out, the BCDDP showed the enhanced ability of modern x-ray mammography to detect a significant number of nonpalpable malignant lesions. These clinically occult tumors are usually

ABBREVIATIONS USED IN TEXT
BCDDP = Breast Cancer Detection Demonstration Project
HIP = Health Insurance Plan of New York

smaller and at an earlier stage than lesions that have grown to sizes detectable by physical examination.[4]

Preliminary reports from two ongoing screening programs have recently been published. In Sweden a randomized controlled study has had similar findings to those of the HIP program, with a greater than 30% reduction in mortality and an increased detection rate of earlier stage lesions for the screened population.[5] Simultaneously, a case-control study in the Netherlands has also found a similar reduction in mortality for the screened population.[6]

Accumulated data show a benefit for screening asymptomatic women 50 years old and older with mammography and physical examination. Controversy, nevertheless, persists because none of the controlled studies has conclusively shown a mortality benefit for women aged 40 to 49 years. Although the results are suggestive in the HIP study, statisticians disagree on the appropriate interpretation of the data for this age group. The Swedish study cannot directly address the question since women 40 to 49 years old were not screened annually, but rather every two years. Breast cancer appears to be faster growing in younger women and the "window" within which earlier detection may have an effect is probably shorter. M. Moskowitz, MD, Professor of Radiology at the University of Cincinnati Medical Center, believes that annual screening is required for women aged 40 to 49 to affect mortality (from an unpublished paper presented at the World Health Organization Breast Imaging Guidelines meeting in Moscow, October 1985). Mammography has improved significantly since the HIP study. Analysis of data from the BCDDP shows the enhanced ability of modern mammography to detect breast cancers in these younger women. In the BCDDP almost twice as many lesions were detected by mammography alone in women younger than age 50 compared with only 19% for mammography alone in the HIP study.[4] Recognition of this has led to the present American Cancer Society screening guidelines.[7]

The prognosis for breast cancer patients directly relates to the stage of the disease at the time of diagnosis.[8,9] Margolin and Lagios have once again shown the ability of x-ray mammography to detect nonpalpable cancers with a concomitant reduction in stage. They examined a mixed population of women between 1974 and 1983, including both symptomatic and asymptomatic patients. In their series, 35% of the cancers detected were found by mammography alone. They achieved this by a well-thought-out combined effort among radiologists, surgeons and pathologists. They constantly reviewed their results, learning from their own experience the value of screening and how to improve on their detection capability. The results of this are shown by the fact that 19% of the tumors detected in the first year were detected by mammography alone, while 41% of the cancers were detected only by mammography in the last year of their report.

This experience once again reinforces the important advantages of mammography, but must remind us of its limitations. *Mammography does not detect all cancers.*[10,11] The breast is a difficult organ to image due not only to the low inherent contrast of the tissue within it, but also to its geometry on the chest wall. Areas of the breast may be hidden by the curve of the thorax and not projected onto the x-ray recording system, be it film screen or xeroradiography. Lesions in the upper inner aspect adjacent to the sternum and laterally in the axilla may not be imaged on routine projections. Rigorous attention by the technologist carrying out the study to positioning the breast will help diminish these "blind areas." The rigid compression of modern dedicated mammographic systems helps to better position the breast over the recording medium. Nevertheless, lesions are missed because they are in an area of the breast that is not imaged.

Another reason for false-negative results on mammography is the fact that normal breast tissue can hide a mass, and, without architectural distortion or clustered microcalcifications, sizable masses can be obscured by the surrounding tissue. In fact, large palpable tumors may not be visible by mammography for this reason and physical examination is still an important factor in breast cancer detection.

Finally, some cancers will be missed because subtle secondary signs of malignancy are missed by the observer. This will always be a source of error as in all observational tests, but by using the proper technique and equipment, this can be minimized by enhancing the visibility of abnormalities.

A negative mammogram does not exclude the possibility of a palpable malignant tumor for the preceding reasons. Although intensive screening by a careful physical examination and high quality mammography will detect a significant number of early stage breast cancers, up to 20% of cancers may go undetected by screening and appear as palpable masses between annual screenings.[4] A negative mammogram and a physical examination showing no abnormalities do not guarantee a cancer-free breast. Both examinations contribute unique information, but can only detect breast cancer, not exclude it.

Mammography is the best *detection* technique presently available, but is not a truly *diagnostic* study. The authors report a predictive value positive for mammography of approximately 30%, which is similar to other reported experiences.[12] Although mammography is specific when lesions have the typical spiculated, ill-defined margins of malignancy, many cancers do not show these primary malignant signs, and secondary changes such as microcalcifications are not always characteristic[13] and may also be found in benign processes. Given the fact that 70% to 80% of *palpable* lesions for which a biopsy was done on clinical suspicion alone prove to be benign,[14] it is reasonable to expect a similar range of predictive value positive for mammography since mammographically detected cancers are frequently at an earlier stage than are those that are palpable. In view of this, mammography should not be specifically considered a diagnostic study, but rather a detection modality. Just as mammography does not obviate the need for careful physical examination, a physical examination that elicits no abnormalities does not reduce the need for mammography. A cooperative effort is required between the clinical examiner and the radiologist to offer the patient the earliest possible detection.

Because mammography will detect a significant number of nonpalpable lesions that prove to be benign, it is incumbent upon radiologists and surgeons to work together closely. The radiologist must use techniques that accurately guide the sur-

geon to nonpalpable areas of concern. Safe, accurate guidance through the positioning of needles or wire guides should be undertaken preoperatively to ensure that the lesion in question is removed and evaluated pathologically while sacrificing the smallest amount of breast tissue to preserve cosmesis. Quadrant resection for nonpalpable lesions and the use of skin markers to guide a surgical procedure are unacceptable due to their inaccuracy and their resultant unnecessary removal of large amounts of breast tissue. Numerous techniques exist to accurately guide a surgeon and these should be used.[15,16]

Mammography is frequently nondiagnostic and a biopsy should be done of a clinically suspicious lesion, in spite of a negative mammogram. Nevertheless, mammography should always be obtained before any breast operation.[17] Given the ability of mammography to detect breast cancer in asymptomatic women, a woman with a palpable abnormality can derive similar benefit from screening. Because most biopsies of palpable masses prove to be benign, screening by mammography before a surgical procedure may show a clinically occult cancer. In women who prove to have cancer, preoperative mammography can detect nonpalpable additional foci of tumor in the ipsilateral breast and this can significantly affect therapeutic decisions. Conservative therapy with lumpectomy and irradiation has a higher risk of failure in women with multifocal macroscopic disease. Mammography must be done preoperatively because postsurgical changes in the breast can greatly alter and obscure tissue definition on a mammogram. Preoperative mammography will also permit the detection of nonpalpable contralateral breast cancers. If the palpable lesion shows primary mammographic signs of malignancy and the subsequent biopsy results are benign, a very early follow-up mammogram should be done to ensure that the lesion in question was in fact excised. Careful review of all lesions with the pathologist will help ensure that the area in question has in fact been properly assessed.[18]

At present, mammography is the only imaging technique with proved efficacy in screening for breast cancer. Ultrasound has a very limited role in the evaluation of focal lesions to determine whether they represent cystic or solid abnormalities.[19] It cannot reliably differentiate between benign and malignant solid lesions, but can be used to guide needle placement for aspiration or guide placement before surgical excision of nonpalpable abnormalities.[20] Ultrasound should not be used to screen for breast cancer since it is unable to detect lesions that are nonpalpable or detectable by mammography and has a concomitant unacceptably high false-positive rate.[21]

Thermography has no proved efficacy for detecting early-stage breast cancer and frequently is negative for small mammographically detectable lesions. Thermography also has a very high false-positive rate and this has prompted the American College of Radiology to state emphatically that there is no role for thermography in screening for breast cancer.[22]

Transillumination techniques (diaphanography, light scanning) are being studied for breast evaluation. Scientific studies reported in refereed journals have to date not shown any efficacy for transillumination in either screening or diagnosis.[23,24] A large-scale phase II study is currently under way to address this issue. Until the information from such a study is available, transillumination should not be used clinically but only as an experimental technique.

Similarly, magnetic resonance imaging is undergoing early evaluation. Preliminary data fail to suggest a role for screening asymptomatic women, and thus far tissue characterization is not of sufficient accuracy to avoid a biopsy of clinically or mammographically suspicious lesions.[25] A great deal of research needs to be done in this area to determine what, if any, role there will be for magnetic resonance imaging in the future for breast evaluation.

We must all insist on a high quality effort because at this time careful mammography and physical examination to detect early-stage lesions appear to have the greatest potential for mortality reduction. At the same time we must recognize the fact that screening will not benefit all women. Some cancers will become systemic before they reach present thresholds of detectability. Other cancers may be indolent and slow growing and not represent a threat to life. Unfortunately, we cannot at this time differentiate such lesions. Screening will benefit the significant number of women whose cancers exhibit a moderate growth pattern and if an appropriate screening interval is applied, the presently available data suggest that there is a "window" in which mortality can be affected. There is already a strong movement within the country toward mammographic screening. We must insist that this be done with high standards and quality control with equipment designed specifically for high-quality mammography.

In view of the importance of containing medical costs, new imaging techniques should not proliferate until efficacy has been clearly shown.[26] At present, mammography is the only imaging technique with proved efficacy for breast cancer screening. Imaging resources should be devoted toward high quality, low cost mammographic screening. Dedicated equipment is required with trained, highly motivated technologists. Screening centers should be opened with the goal of producing high quality imaging. Early detection can be achieved only in this way. Radiologists must be trained and gain experience in mammographic interpretation and a close cooperative effort among radiologists, surgeons and pathologists must be developed.

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What Is Medicine (Organized Medicine) Really All About?

COUNTY AND STATE MEDICAL ASSOCIATIONS and the American Medical Association itself—organized medicine—have accepted the responsibility to serve as the overall professional organizations to promote the interests of all physicians and to contribute professional expertise to the health care needs of society as a whole. In these times this is not an easy role. Democratically structured as they are, these organizations respond to their members, especially to the squeaky wheels among them, many of whom are understandably concerned about their turf in practice, about malpractice and its costs and about their sometimes too evidently receding incomes. These medical associations also try to respond to the third party interventions into medical practice and patient care that affect all who practice medicine, and try to protect the authority of physicians to carry out their professional and legal responsibilities. Then there are the social, economic and political forces that impinge in many ways upon medical practice and the professional interactions that take place between doctors and their patients. These forces are powerful, and too often seem relatively insensitive to the particular needs of individual patients, not to mention physicians. And now, most recently, organized medicine has formally assumed a responsibility of advocacy for patients in all of the social, economic and political arenas of health care. This, of course, is simply an extension of a physician's traditional interest in what is best for his or her patient.

The going has not been easy for organized medicine. Some of the reasons may be worth noting. Physicians are no longer the powerful force in society they once were. Their opinions and recommendations no longer go almost unchallenged. Organized medicine is only one voice among many in today's society. In the economic sphere the dollars that physicians can command are no match for the dollars that are or can be controlled by others in health care. Their political action committee (PAC) dollars, however, have been remarkably well used to assure that legislators at least listen to physicians' views. But at the ballot box their votes hardly count at all, and this is not lost sight of by politicians. The battle for influence in these arenas has been an uphill one because the basic power to assure success is really not there. Viewed in this way, the social, economic and political accomplishments of organized medicine have been very considerable indeed.

But are these accomplishments—remarkable as they are—really enough, or all that they could or should be? If it is true that the profession's social, economic and political battles are being fought by organized medicine from positions of relative weakness, then is there any way this might be changed and some greater influence of the medical profession brought to bear? When one thinks about it, a unique and very considerable strength lies in its unquestioned expertise in the art and science of medicine. Organized medicine has yet to make this fully its own, and has yet to find ways to use the full power of this inherent expertise in the profession's forays into the social, economic and political areas of health care. A second unique and potentially equally powerful strength for organized medicine is the role of patient advocacy recently espoused by most of its organizations. New skills and new techniques will need to be developed for both of these strengths to be used with full effectiveness in the societal arenas of health care. It is also worth noting that both medical expertise and patient advocacy can be readily supported by all physicians whether in or still outside organized medicine. This is part and parcel of daily patient care. The public also respects the expertise of the medical profession in the art and science of medicine, and everyone, of course, expects physicians will act in the best interests of patients. It would seem both natural and logical if the profession as a whole, represented by organized medicine, were to begin now to make greater use of these powers inherent in the profession in the public arenas of health care, where it is now spending so much of its energy and resources in what has been such an uphill battle. And, after all, is this not what medicine (organized medicine) is really all about?

Some may ask more specifically for an example of how this might work in practice. One possibility might be that if organized medicine were to take the lead in weeding out unneeded, outmoded, ineffective and potentially harmful (as well as costly) procedures and treatments in health care, it would be bringing the strengths of its professional expertise and its patient advocacy to bear, and it would improve the quality of care and also reap social, economic and political benefits for the profession in these more public arenas of health care. And it should also be well received by both patients and the public. This is just one example. There is a world of opportunity.

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Imaging Modalities for Lymph Nodes

THE RADIOLOGIC EVALUATION of lymph node disease has undergone drastic changes in the past three decades. Since its inception in the 1960s, bipedal lymphangiography has always assumed a primary role in the staging of a variety of abdominal and pelvic neoplasms. Although invasive and somewhat uncomfortable to patients, the major advantage of